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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,715	04/30/2001	George Jackowski	2132.030	3820

21917 7590 01/03/2006  
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EXAMINER
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SKIBINSKY, ANNA

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/845,715		JACKOWSKI ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Anna Skibinsky		1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 36-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 36-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                                    |

### **Detailed Action**

Applicants' arguments, filed November 14, 2003, have been fully considered but they are not deemed persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

#### ***VAGUE AND INDEFINITE***

1. Claims 1 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "diagnostic for myocardial ... heart failure (CHF)" which is non-essential descriptive subject matter. This phrase recites an inherent property of the peptide and does not further limit the structure itself. This is deemed to be vague and indefinite. Clarification of the meets and bounds of claim 1 is requested.

Claim 36(b) recites "a manner effective to maximize elucidation of discernible peptide fragments," which is deemed vague and indefinite. This is not a positive method step which clearly sets forth how this particular method step is carried out. While the claims are read in light of the specification, limitations from the specification cannot be read into the claims. This entire phrase appears unnecessary. It is unclear what such a "manner", as stated specifically in claim 36, would be. Clarification of the meets and bounds of the claim language is requested.

Claim 36(c) recites wherein "recognition of a mass spectrum profile ... displaying the characteristic profile of the mass spectrum profile " which is deemed to be vague and indefinite. The claim language seems unnecessarily wordy and confusing as to the distinction between the various mass spectrum profiles recited in said claim. Additionally, the term "recognition" implies a process in the human brain, and not a computerized step. The profile does not "display" anything, "characteristic profile" is a relative term which appears to be changeable, and the end of the claim sets forth "is diagnostic ..." which again (as above) is unessential descriptive subject matter.

Steps which clearly "a) obtain a sample; b) perform mass spectrometry; c) identify the presence or absence of the peptide consisting of amino acid residues 2-12 of SEQ ID NO:1, and diagnose myocardial infraction ... base on the presence of said peptide in the sample profile," would be more clear.

Clarification of the meets and bounds of the claim language is requested.

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**NEW MATTER**

2. Claims 41-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection in the previous Office Action filed November 14, 2003 is upheld. The instant specification recites that "the marker sequences of the present invention" may be used as antigens in immunoassays (page 31, lines 13-16). However, there is no direct correlation of the "immunoassays" with a kit such as that recited in claim 41. Immunoassays may be used in a plurality of devices and are not limited to use within a diagnostic kit. Specifically, a diagnostic kit comprising amino acid residues 2-12 of SEQ ID NO:1 is not recited in the specification and the specific page and line in the specification was not pointed to in the Arguments/Remarks filed May 16, 2005. Therefore, the diagnostic kit comprising the marker sequence consisting of amino acid residues 2-12 of SEQ ID NO:1 is deemed New Matter.

***Claim Rejections - 35 USC § 101***

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The amino acid residues 2-12 of SEQ ID NO:1 are specified, for example to be "isolated" and/or "purified" and therefore do not indicate the hand-of-man.

### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Skibinsky whose telephone number is (571) 272-4373. The examiner can normally be reached on 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
MARY K. ZEMAN  
PRIMARY EXAMINER

AW1631  
12/21/05